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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,195	09/14/2000	Keith H. Johnson	2000200-0003	2403

7590 06/08/2005

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EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/662,195

Applicant(s)

JOHNSON, KEITH H.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-11 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-11, and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt of Amendment and Remarks filed March 29, 2005 is acknowledged. Claims 1-3, 6-11, and 15-25 are pending in this application.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments of 3/29/05.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-3, 6-11, and 15-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Roessler et al (PGPUB 2002/0155084).**

Roessler discloses nanoemulsion form and methods of delivering biological agents to the skin. The nanoemulsions comprises water, oil, and a surfactant mixture. See claim 1.

Specifically, [0087] discloses a water-in-oil nanoemulsion that may contain a biological active agent. See [0171] also. The aqueous component is present in the amount of 0.1-35% and the oil component is present preferably in the amount of 0.1-95%. See [0075-0076]. The preferred oils for the oil phase are soybean oil and olive oil. See [0075]. Table 1 discloses non-ionic surfactants that are utilized in the instant invention, including the instantly claimed surfactants in the instant

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amount [0077]. The biological agent may be selected from proteins, carbohydrates, lipids (which would necessarily be in the oil phase, and nucleic acids. See [0094]. The composition may be in a gel, lotion, or cream form. See [0016].

Note it is the examiner's position after a careful review of the instant disclosure and in light of applicant's remarks in the interview that the surfactants themselves provide the instantly claimed water structure, i.e. pentagonal dodecahedral water clusters. The examiner points to page 4 of the instant specification wherein applicant discloses "The water nanoclusters of the present invention can be produced by a variety of means....However, for the purposes of this invention, use of surfactant to produce desired nanoemulsions as described below is most preferred."

Further the examples in the instant specification merely combine regular water, oil, and surfactants to provide the instant w/o emulsions with the instant clusters. Additionally, the examiner points to US 5,800,576 wherein Johnson et al discloses on column 7, lines 50-55 that "chemical method for producing water clusters comprising pentagonal dodecahedral structures include the use of surfactants or clathrating agents." If applicant contends the surfactants do not inherently produce the instant clusters, it is the applicant's burden to rebut the examiner's position with **evidence**. See MPEP 2112.

**Claims 11, 15-18, 21, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ying et al (6,413,489).**

Ying et al disclose water-in-oil nanoemulsion containing at least 5% water, trimethylpentane (hydrocarbon oil), a surfactant (polyethoxylated alcohol surfactant, and a cosurfactant (1-pentanol). One example comprises 10% water, 75% trimethylpentane, 11% surfactant, and 4% cosurfactant. See example 1 and Table 1.

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Note it is the examiner's position after a careful review of the instant disclosure and in light of applicant's remarks in the interview that the surfactants themselves provide the instantly claimed water structure, i.e. pentagonal dodecahedral water clusters. The examiner points to page 4 of the instant specification wherein applicant discloses "The water nanoclusters of the present invention can be produced by a variety of means....However, for the purposes of this invention, use of surfactant to produce desired nanoemulsions as described below is most preferred." Further the examples in the instant specification merely combine regular water, oil, and surfactants to provide the instant w/o emulsions with the instant clusters. Additionally, the examiner points to US 5,800,576 wherein Johnson et al discloses on column 7, lines 50-55 that "chemical method for producing water clusters comprising pentagonal dodecahedral structures include the use of surfactants or clathrating agents." If applicant contends the surfactants do not inherently produce the instant clusters, it is the applicant's burden to rebut the examiner's position with **evidence**. See MPEP 2112.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
Art Unit 1616

SSG

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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